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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MCKENZIE, THOMAS C

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. This action is in response to an application filed on 11/17/03. There are twenty-one claims pending. Claims 1-11 are compound claims. Claim 14 is a composition claim. Claims 15-21 are method of using claims. The application concerns some tricyclic fused pyrazine compounds, compositions, and uses thereof.
2. The present application is a daughter of application 09/986,607 and a granddaughter of application 09/129,139. There was a restriction in the grandparent case between compound claims and use claims as well as an election of species. There was just an election of species in the parent case. Since both parent and grandparent cases have matured into patents, the restriction below was designed in part to avoid previously patented subject matter but to completely cover the presently claimed subject matter. Examiner Ambrose, who was involved in the grandparent case, has been detailed to another part of the USPTO. Examiner Wright, who was involved with the parent case, is no longer with the USPTO. The present case has been assigned to Examiner McKenzie.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims parts of 1-14, drawn to fused oxazole compounds *etc.* of the formula of claim 1 with $B = C$ and A and $D = N, O, \text{ or } S$, classified in class 544, subclass 345.
- II. Claims parts of 15-21, drawn to therapeutic uses of the fused imidazole compounds of the formula of claim 1 with $B = C$ and $A = D = N$ classified in class 514, subclass 250.
- III. Claims parts of 1-14, drawn to fused cyclopentadiene compounds of the formula of claim 1 with $B = C$ and $A = D = C$, classified in class 544, subclass 344.
- IV. Claims parts of 1-14, drawn to fused oxadiazole compounds *etc.* of the formula of claim 1 with $B = N, O, \text{ or } S$ and A and $D = C, N, O, \text{ or } S$, classified in class 544, subclass 345.
- V. Claims parts of 15-21, drawn to therapeutic uses of the fused furan *etc.* compounds of the formula of claim 1 with $B = C$ and A and $D = C, O, \text{ or } S$ classified in class 514, subclass 250.

VI. Claims parts of 15-21, drawn to therapeutic uses of the fused triazole *etc.* compounds of the formula of claim 1 with B = N, O, or S and A and D = C, N, O, or S classified in class 514, subclass 250.

Please note the subject matter of Group I corresponds to the claims of the grandparent application, now US Patent No. 6,329,375.

Please note the subject matter of Group II corresponds to the claims of the parent application, now US Patent No. 6,656,940.

4. The inventions are distinct, each from the other because of the following reasons: inventions I, III, and IV and II, V, and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case breast cancer treatment, one of the claimed therapeutic uses, may be accomplished with Taxol, a compound unrelated to those of the present application. In addition, claims 17 and 18 are drawn to treatment of 33 distinct diseases. Thus, Applications admit their compounds can be used in a number of materially different processes.

5. The heterocyclic core of the structure given in claim 1 is the tricyclic ring containing atoms A, B, and D. This ring is a mandatory feature and has multiple possible heteroatoms. These multiple claimed rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I and IV and inventions II, V, and VI although classified together have acquired a separate status in the art as shown by their different names. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and Groups I and III acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Should Applicants traverse the restriction requirement on the grounds that the different core rings are not patentably distinguishable, Applicants should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence may be used in a rejection under 35 USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims

in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.


8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

10. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

11. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, SPE of Art Unit 1624, at (571)-272-0661.


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